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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/646,682	08/22/2003	Dennis S. Fernandez	FERN-P013	1019

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EXAMINER	
DEJONG, ERIC S	

ART UNIT	PAPER NUMBER
1631	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/646,682	FERNANDEZ, DENNIS S.	
	Examiner	Art Unit	
	ERIC S. DEJONG	1631	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *02/12/2009*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *36-55* is/are pending in the application.

4a) Of the above claim(s) *50* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *36-49 and 51-55* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *12/08/2008 and 12/08/2008*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED OFFICE ACTION

Applicants response filed 02/12/2009 is acknowledged.

Claims 1-35 are cancelled. Claims 36-55 are pending. Claim 50 is withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected species, there being no allowable generic or linking claim. Election was made **without** traverse in the reply filed on 02/15/2008. Claims 36-49 and 51-55 are currently under examination.

Rejections and/or objections not reiterated from previous office actions are hereby withdrawn. The following rejections and/or objections are either reiterated or newly applied. They constitute the complete set presently being applied to the instant application.

Information Disclosure Statement

The information disclosure statements (IDS) submitted on 12/08/2008 are acknowledged. Accordingly, the information disclosure statements have been considered by the examiner and a signed copies of the associated PTO-1449 forms have been included with this Office action.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 36-49 and 51-55 are rejected under 35 U.S.C. 103(a) as being unpatentable over Porat et al. (US Patent No. 6,432,050) in view of Giuffre (US Patent No. 6,024,548). This rejection is maintained and reiterated from the previous Office action.

The instant claims are drawn to an integrated biosensor and simulation system and method of use. The system comprises an implantable biosensor, and a simulator comprising a systems-biology platform for generating a therapeutic or diagnostic output, wherein said simulator is reconfigurable by said simulator, such reconfiguration thereby reconfiguring a biocatalyst chip, a logic device, a tissue scaffold, a therapeutic reservoir, or a DNA microarray. The related method of use comprises the steps of sensing a biological target to generate a signal, simulating using said signal and a model of the biological target to generate a therapeutic or diagnostic output.

Porat et al. sets forth systems and methods of use for an implantable biosensor system for monitoring and optionally alleviating a physiological condition in a patient (see Porat et al., Abstract and throughout). Porat et al. further teaches the that the implantable biosensor is used to generate a signal comprising information pertaining to a patients physiological condition (see Porat et al., col. 3, lines 35-61). Porat et al.

further teaches embodiments wherein the an implantable biosensor system comprising a shunt a having fluid passageway and being operable for draining fluid through a fluid passage way from a portion of the patient body (see Porat et al., col. 3, line 62 through col. 4, line 19), which reads on a reconfigurable sensor, wherein reconfiguration involves reconfiguring a therapeutic reservoir as instantly claimed.

While Porat et al. teaches the activation of the above described implantable, reconfigurable biosensor involving a shunt having a fluid passageway, Porat et al. teaches that the activation of said shunt is based on monitored physiological conditions. Porat et al. does not expressly teach the use of a simulator comprising a system-biology platform and a model to generate a therapeutic or diagnostic output, whereby a biosensor is reconfigured by a simulator.

Giuffre discloses a method and a system for registering changes in brain and central nervous system activity by using simulation and signals derived from biosensors (*e.g.*, cardiovascular signal) (See Giuffre, Abstract, col. 4, lines 6-17, and claims 1, 5, 7, 8, 12, and 18). Giuffre discloses generating a signal of a biological target by a biosensor (col. 9, lines 26-37), which reads on a sensor, as recited in claims 36 and 40, and the process step of sensing a biological target to generate a signal, as recited in claim 40. Giuffre discloses a programmable computer systems for simulation of brain activity using a signal data and a model to estimate brain and central nervous system activity (see Giuffre, col. 4, line 6 through col. 5, line 11), which reads on a simulation comprising a system-biology platform, as recited in claims 36 and 40, and the process step of simulating using the signal and a model of the target to generate a therapeutic or

diagnostic output, as recited in claim 40. Further, the instant specification is relied upon for determining the scope of a "systems-biology platform" (see page 36, line 16-20), as a system that uses software for analyzing computational behavior of a biological system. Giuffre discloses embodiments of trained neural net and self-teaching computer systems that act in real-time to incrementally perturb a system and/or change models until data management is optimal (see Giuffre, Fig 3., col. 4, lines 6-60 and col. 6, lines 53-59), which reads on a sensor reconfigurable by a simulator, as recited in claims 36 and 40, and the process step of a simulator reconfiguring a sensor, as recited in claim 40.

Giuffre further teaches the detection of drug infusions and drug and alcohol levels in the blood for use in the disclosed method and a system for registering changes in brain and central nervous system activity (see Giuffre, col. 7, line 44 through col. 8, line 2), which reads on a sensor that senses a food material for consumption by a biological target, the generation of a second signal therefrom, and the use of said second signal to generate a therapeutic or diagnostic output as recited claims 37 and 41. Giuffre teaches generating an output according to a regulatory condition by the disclosed simulation system (see Giuffre, col. 7, line 44 through col. 8, line 24), as recited in claims 38 and 42. Giuffre discloses coupling using a trained neural net and self-teaching computer systems (a switch) (see Giuffre, Figs. 1-3 and col. 4, lines 6-60), which reads on a sensor coupled to a simulator via a programmable switch as recited in claims 39 and 43.

Giuffre further teaches the use of separate biosensors for the heart and brain (see Giuffre, col. 4, lines 6-38), which reads on the implantation of a biosensor for the heart and brain, as recited in claims 44 and 52, an array of at least two sensors capable of sensing two different biological targets, as recited in claims 45, 46, 49, 53, and 54, and a neural biological target, as recited in claims 47 and 55. Giuffre further teaches that the disclosed method relies upon neurophysiological and cardiovascular monitoring from said biosensors for training a neural network (see Giuffre, col. 3, lines 55-61 and col. 4, lines 6-60). Following the training of a neural network, Giuffre further teaches that only cardiovascular monitoring by heart associated biosensor and the trained neural network are relied upon to estimate the neurophysiological state of a patient (see Giuffre, col. 4, lines 17-38), which reads on the elected species of reconfiguration comprising activating or deactivating at least one biosensor, as recited in claims 48, 49, 51, and 54.

Therefore it would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains to combine the biosensor system and methods, set forth by Porat et al., in combination with the method and a system for registering changes in brain and central nervous system activity by using simulation and signals derived from biosensors, as taught by Giuffre. One of ordinary skill in the art would further be motivated to combine the systems and methods set forth by Porat et al. with that of Giuffre because Giuffre teaches that systems that can predict brain states using already implemented cardiovascular

monitoring modalities will allow for predictive capabilities while minimizing risk, cost, and added complexity of such setups (see Giuffre, col. 1, lines 5-25).

Response to Arguments

Applicant's arguments filed 02/12/2009 have been fully considered but they are not persuasive.

In regards to the rejection of claims under 35 USC 103(a) as being unpatentable over Porat et al. in view of Giuffre, applicants argue that the instant claims have been amended to recite a system-biology platform to further distinguish the instant claims over the applied prior art of Giuffre.

In response, it is reiterated from the instant rejection that the instant specification has relied upon for determining the scope of a "systems-biology platform" (see page 36, line 16-20), as a system that uses software for analyzing computational behavior of a biological system. Since the programmable computer systems for simulation of brain activity using a signal data and a model to estimate brain and central nervous system activity as disclosed by Giuffre (see Giuffre, col. 4, line 6 through col. 5, line 11) meets the functional operations a systems-biology platform as set forth in the instant disclosure, it is maintained that the instant claims are not differentiated over the prior art of record. Therefore applicants argument is not persuasive.

Conclusion

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to ERIC S. DEJONG whose telephone number is (571)272-6099. The examiner can normally be reached on 8:30AM-5:00PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Marjorie Moran can be reached on (571) 272-0720. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/ERIC S. DEJONG/
Primary Examiner, Art Unit 1631